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MDSCOPE®

Video Otoscope

MS101

User's Manual

UM-AP0902-01-B

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When there is a need to immediately report an adverse effect in connection with operation of the MDSCOPE® Video Otoscope, please contact the authorized representative or the agent. You may also contact the customer service at +886 2 2999-5505 or MDSCOPE@appleBMI.com

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Harvest Consulting Corp.
2904 N, Boldt Drive, Flagstaff
Arizona 86001, U.S.A.

EC REP
Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover
Germany

Thank you for choosing the MDSCOPE® Video Otoscope, the Video Otoscope choice for health care professionals. The operating and maintenance instructions found in this manual should be followed to ensure product reliability. Please read this manual carefully before using the product.

If you experience a technical problem related to operation of the MDSCOPE® Video Otoscope, please contact your local dealer for the after-sales support. You may also contact the customer service at +886 2 2999-5505 or MDSCOPE@appleBMI.com

FDA listed:
D083901, D119968
IEC 60601-1, IEC 60601-1-2

CE The manufacturer declares on his/her sole responsibility that the product is in conformity with the essential requirements of the 93/42/EEC Medical Device Directive, and that the relevant conformity assessment procedures have been fulfilled.

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1 Introduction

The MDSCOPE® Video Otoscope is a hand-held medical device that includes a video camera for capturing a video image of the outer ear canal and/or tympanic membrane. The image is displayed directly on a built-in screen or displayed on an external display device via connection to a video out port. The MDSCOPE® video otoscope is preset for its focus, brightness level and white balance. It is powered by two AA batteries for a continuous operation of about 4 hours.

Video imaging provides several advantages over direct visualization. The MDSCOPE® video otoscope may be operated with an image dongle to record the otoscopic images which are used to create medical history for each patient. By using the MDSCOPE® video otoscope, health professionals can review and discuss the clinical findings with patients to enhance the doctor/patient interaction.

Intended use
The MDSCOPE® video otoscope is as an assistive tool to observe the health condition of the ear. Indications for use include:

- Inspection of the outer ear canal
- Inspection of the tympanic membrane
- Inspection of hearing aid devices

The MDSCOPE® video otoscope should not be used for any other purposes.

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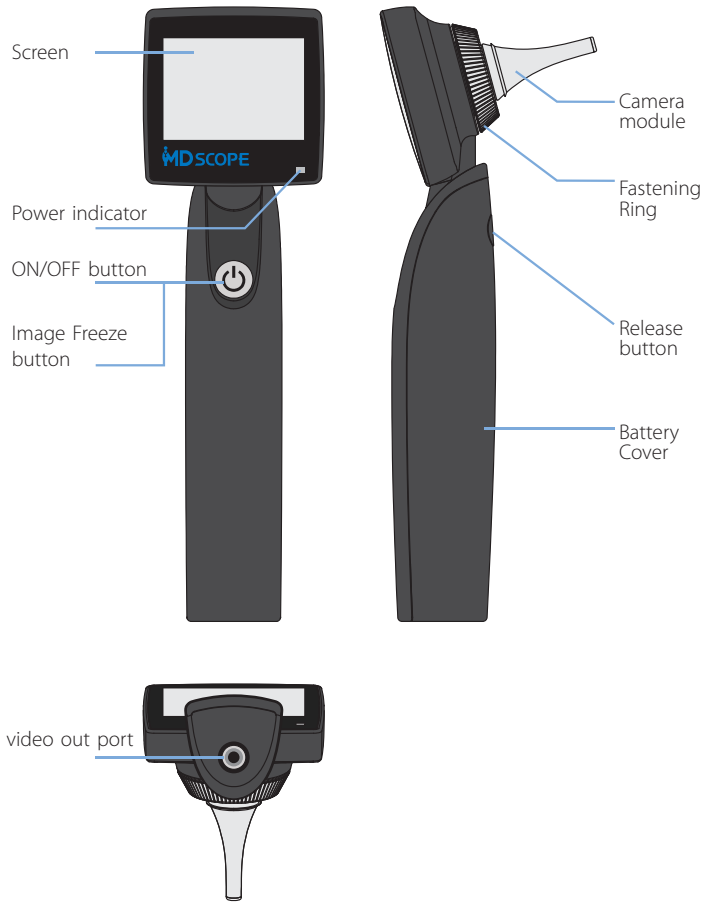
MS101 features



Symbols

Safety Symbols

Manufacturer

Caution

SN

Serial number

IPXØ

Not protected against the ingress of water

Type BF

+49°C
-20°C

Temperature limits

EC REP

Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

CE

CE mark has been identified according to Article 17 of the MDD(93/42/EEC)

Consult instructions for use

Button Symbols

Power

PRESS

Press

Video out

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Saftey and Cautions

The MDSCOPE® video otoscope should be operated under supervision of a trained ENT doctor or health professionals with sufficient knowledge of otoscopy.

***Do not use this device in the presence of inflammable anesthetics.**

*Please follow local rules and regulations regarding disposal or recycling of the device and its components.

*The Video signal output (RCA Port) connector is intended for connection to devices that comply with IEC 60601-1, or other IEC standards (for example, IEC 60950), as appropriate to the device.

*To minimize external otoscope housing temperatures, the device is suggested to turn on for no more than 3 minutes. The device must then be turned off for a minimum of 3 minutes before turning it back on again.

*Do not apply alcohol, chemicals, or water to clean the lenses. Solution entering the optical assembly can cause short-circuits for electrical components.

*Portable and mobile wireless communications device which transmits radiofrequency (RF) may affect the performance of the medical electrical device.

Suggested Use of Long/Flexible Camera module (For User purchasing the long/flexible camera modules)

The long camera module is selected when it is difficult to get near to the target using the standard camera module. As the MDSCOPE® video otoscope is operated with the long camera module, the user needs to ensure that the tip of the camera module is held a distance NOT less than 1cm away from the target in the ear canal.

The flexible camera module is selected when it is difficult to get near to the target using the long camera module. As the MDSCOPE® video otoscope is operated with the flexible camera module, the user needs to ensure that the tip of the camera module is held a distance NOT less than 1cm away from the target in the ear canal.

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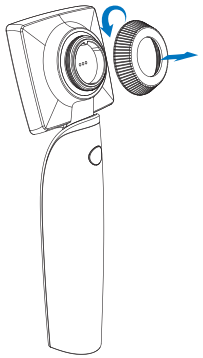
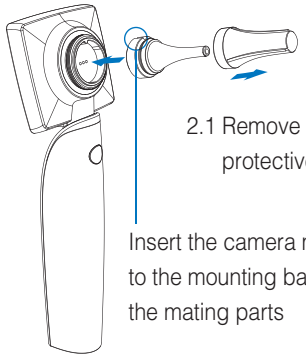
2 Operations

Setting up the Video Otoscope

1. Remove the fastening ring.



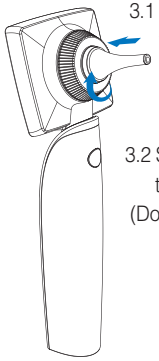
2. Align the camera module to the mounting base.



2.1 Remove the protective cover.

Insert the camera module to the mounting base via the mating parts

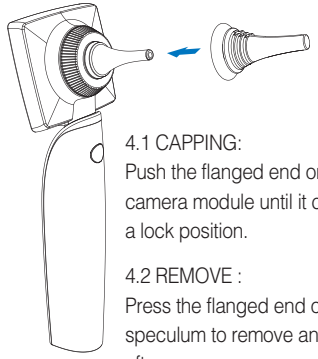
3. Screw on the fastening ring.



3.1 Align the fastening ring.

3.2 Screw it down to tighten. (Do not overtighten)

4. Put on new speculum before using.

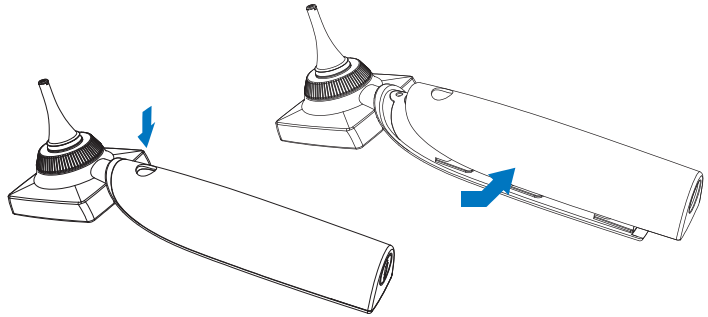


4.1 CAPPING:
Push the flanged end onto the camera module until it clicks into a lock position.

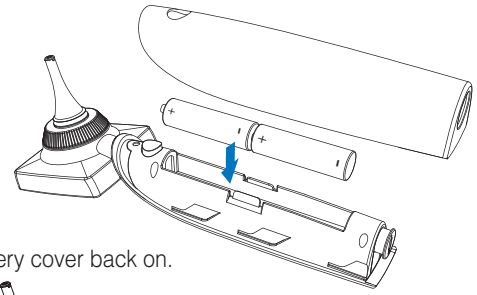
4.2 REMOVE :
Press the flanged end of the rigid speculum to remove and discard after use.

Loading the Batteries

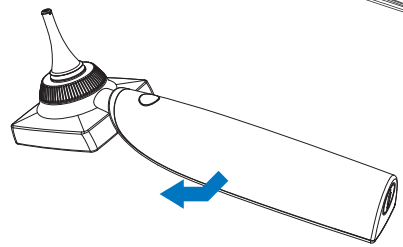
1. Push the release button.
2. Slide down to open the battery cover.



3. Load in the batteries.



4.Put the battery cover back on.



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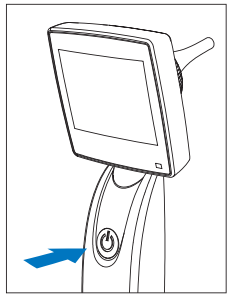
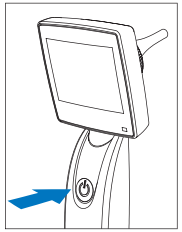
Power ON/OFF



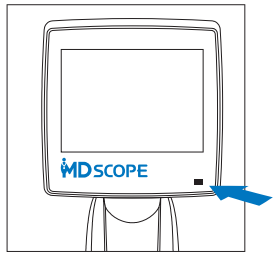
Press and hold the power button for 2 seconds to switch the device on.

Image Freeze / Release Function



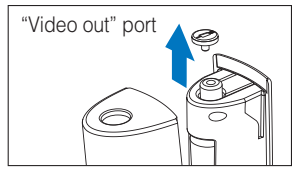
When the power is turned ON, Press the image freeze button for less than 1 second to freeze the image, and press the same button again to return to preview mode.

Battery Conditions

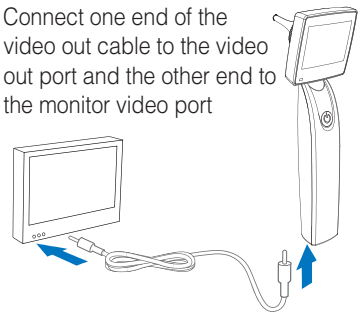


When the light switches from green to red, it indicates that the batteries are low. In this case, please change batteries.

Video Out Function



1. Remove the battery cover.
2. Remove the video out cover.
3. Connect one end of the video out cable to the video out port and the other end to the monitor video port



3 Specifications

Item	Specifications
Dimensions (approximate)	Length : 7.5 cm (3") Width : 6.3 cm (2-1/2") Height : 21.2 cm (8-3/8")
Focal length/distance	1 to 4 cm away from target
Weight	Approximately 180 g
Batteries	2 x AA Alkaline batteries
Display size	2.4" TFT LCD
Video out	NTSC system
Operating Temperature	+10° C to +40° C (+50° F to +104° F)
Shipping / Storage Temperature Relative humidity	 -20° C to +49° C (-4° F to +120° F) 50% to 75% non-condensing
Predicted product life	2 years

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4 Cleaning and Storage

For cleaning of the camera probe

1st Step: Take out the alcoholized pre-pad.

2nd Step: Clean and wipe the stainless steel part of the standard/long camera module or the outer sheath of the flexible camera module with the alcoholized pre-pad.

3rd Step: Gently clean the camera lens with the cotton swab.

Care should be taken not to scratch the lens of the camera module.

For cleaning of the main unit

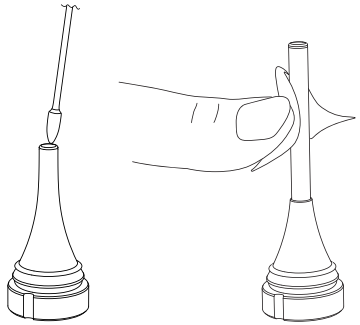
The housing of the main unit can be cleaned with a cloth dampened with water, alcohol, or a non-staining disinfectant.

Liquids should not be dripped or spilled over the surfaces of the LCD module or handle as they are not watertight.

Storage

The camera module and main unit should be placed in the storage compartment of the carrying case.

Unnecessary exposure to extremes in temperature and humidity should be avoided.



5 Troubleshooting

1. Why is the MDSCOPE® video otoscope not switched ON?

☐ 1. Please confirm the batteries have power and reload the batteries in the battery compartment.

☐ 2. Check and confirm the batteries are positioned in correct orientation.

☐ 3. Check and confirm the button can be depressed with ease, and repeat at least 10 times.

☐ 4. If the device is NOT switched ON by repeating the above steps, please contact your local dealer for technical supports.

2. After the device is switched ON, the power indicator light is ON but no image is displayed or the image is fuzzy and unstable.

☐ 1. Confirm if the LED light in front of the camera module is switched ON.

☐ 2. Confirm if camera module is mounted properly.

☐ 3. Confirm if the fastening ring is tightened up.

☐ 4. Confirm if there is any foreign substance stuck on the metal contact and clean the surface of metal contact with alcoholized pre-pad.

☐ 5. If the image is still NOT displayed properly after carrying out steps 1-4 above, please contact your local dealer for technical supports.

3. The device is switched ON with image displayed but I can't freeze the image.

☐ 1. Restart the device and try the freeze function again.

☐ 2. Check and confirm the button can be depressed with ease, and repeat at least 10 times.

☐ 3. The main unit may be defective if the freeze function does not work after repeating the above steps for several times. Please contact your local dealer for technical supports.

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6 Parts

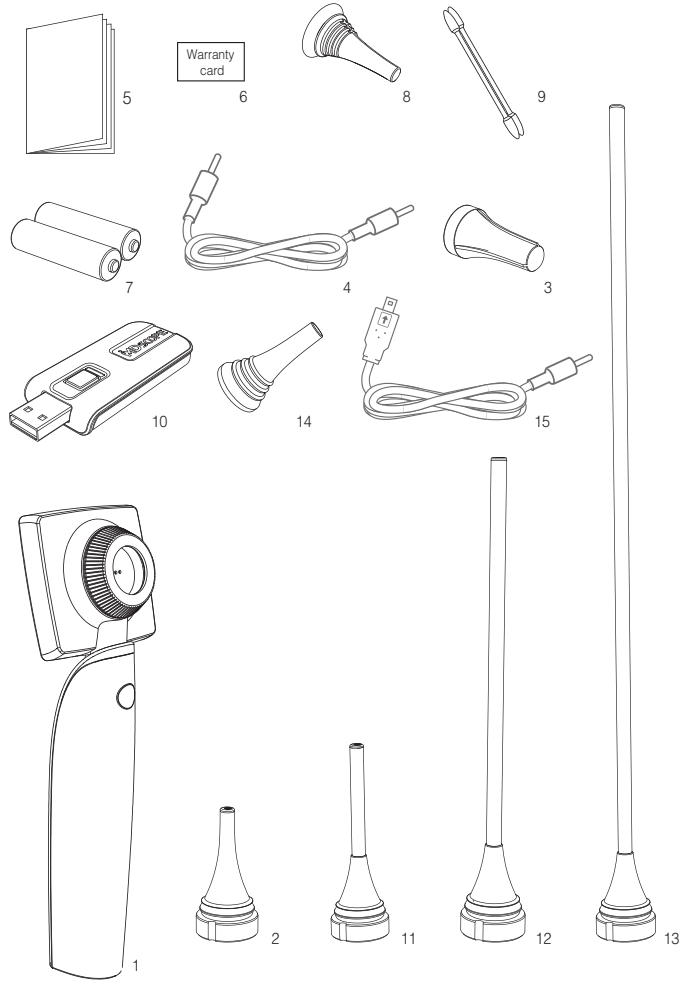
Basic Parts

Item	Number	Description	Quantity
1	MS101-001	Main device	1
2	MS101-002	Camera module (45mm)	1
3	MS101-003	Protective cover	2
4	MS101-005	Video cable	1
5	MS101-006	User manual	1
6	MS101-007	Warranty card	1
7	MS101-008	“AA” Alkaline batteries	2
8	MS101-016	Disposable Specula	24
9	MS101-017	Cotton Swab	25

Optional Parts

Item	Number	Description	Quantity
10	MS101-011	Image Dongle With USB cable	1
11	MS101-012	Long camear module (75mm)	1
12	MS101-013	Camera module (150mm)	1
13	MS101-014	Camera module (300mm)	1
14	MS101-015	Disposable Specula	250
15	MS101-018	Cable Set	1

Parts List



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7 Limited Warranty

Each of the MDSCOPE® video otoscope comes with a one-year warranty, starting on the purchase date to cover repair and/or if necessary replacement of any product failure due to defects in materials and workmanship. Within the limited range of the warranty, defective products shall be repaired or replaced by the Manufacturer or authorized technical and service groups at their options and to the extent permitted by law.

This warranty is non transferable. Damages due to negligence, accident, abuse, misapplication, modification, or repairs not made by the Manufacturer, or authorized technical and service groups, are not covered by the warranty. Within the coverage of the warranty, the delivery fee for mailing to the local dealer or the direct store is not covered within the scope of the warranty.

EU Representative:
Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover
Germany

Manufacturer:
APPLE BioMedical Inc.
8th Floor, No.12, Lane 609, Chong Shin Road Sec.5, New Taipei,
24159, Taiwan. TEL : +886 2 2999 5505 FAX : +886 2 2999 6605
E-mail : MDSCOPE@appleBMI.com
Website : www.MDSCOPE.net

Appendix

Table 201
Guidance and manufacture's declaration-electomagnetic emissions

The MDSCOPE® video otoscope is intended for use in the electromagnetic environment specified below. The customer or the users of the device should assure that it is used in the such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

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Table 202
Guidance and manufacture's declaration-electomagnetic immunity

The MDSCOPE® video otoscope is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative air humidity must have 30 % at least.
Electrical fast transient /bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60% dip in UT) for 5 cycle s 70 % UT (30% dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 s	Not Applicable	
Power frequency magnetic field IEC 61000-4-8	3 A/m	0,3 A/m	If image distortion occurs, it may be necessary to position the device image intensifier further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE : UT is the a.c. mains voltage prior to application of test level.

Table 204
Guidance and manufacture's declaration-electomagnetic immunity

The MDSCOPE® video otoscope is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1,2\sqrt{P}$ $d=1,2\sqrt{P}$ 80MHz to 800 MHz $d=2,3\sqrt{P}$ 800 MHz to 2,5 GHz where $\boldsymbol{P}$ is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer and $\boldsymbol{d}$ is the recommended separation distance in meters(m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range[b] . Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1: At 80 Hz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptions and reflections from structures, objects and people.

[a] Field strength from transmitters such as base stations for radio (celluar/cordes) telephones and mobile radio, amateur radio, AM and FM radio and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

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Table 206
Recommended separation distances between portable and mobile RF communications equipment and the MDSCOPE® Video Otoscope

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to the frequency of transmitter m**		
	150 kHz to 80 MHz $d=1,2\sqrt{P}$	150 kHz to 80 MHz $d=1,2\sqrt{P}$	150 kHz to 80 MHz $d=1,2\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in the meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

NOTE 1: At 80 Hz and 800 MHz the separation distance for the frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptions and reflections from structures, objects and people.

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